



Delaware Division of Public Health Community-Based Naloxone Access Program Standing Orders



*DELAWARE HEALTH
AND SOCIAL SERVICES*
Division of Public Health

Effective: June 27, 2018

Approved by the Board of Medical Licensure and Discipline: June 5, 2018



Signature

June 26, 2018

Date

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Director
Division of Public Health**

**Community-Based Naloxone Access Program
Medical Director**

Community-Based Naloxone Access Program

Nasal Naloxone Distribution and Administration

Community Responder Naloxone (Narcan®) STANDING ORDERS

Approved for use by the Community-Based Naloxone Access Program's participating agencies, participating pharmacies, and trained responders

INDICATIONS: Respiratory distress as evidenced by slow respirations or no breathing (apnea), or unresponsiveness to stimuli (such as shaking, yelling or sternal rub). This protocol will allow trained Opioid Overdose Responders to treat persons with a history based on bystanders, or Responder's prior knowledge of the person, or suspicion of potential opioid overdose as evidenced by nearby medications or drug paraphernalia.

Naloxone (naloxone hydrochloride) is indicated for reversal of opioid overdose in the setting of respiratory depression or no breathing (apnea) or unresponsiveness. It may be delivered intranasally with the use of a mucosal atomizer device.

Order to dispense:

- This standing order authorizes approved Community-Based training programs and participating pharmacies to distribute nasal naloxone kits to persons who have completed CBNAP Opioid Overdose Responder Training.
- This standing order authorizes approved Community-Based training programs to maintain supplies of nasal naloxone kits for the purposes of distributing them as part of the Community-Based Naloxone Access Program.
- Pharmacists should consider offering training and nasal naloxone kits to patients who have been prescribed 50 or more morphine milligram equivalents (MME) per day.
- Upon completion of CBNAP Training and documentation, dispense for use by an Opioid Overdose Responder a nasal naloxone kit.

Nasal naloxone kits contain the following at a minimum:

- Two labeled (*to meet Board of Pharmacy standards*) Naloxone HCL 2mg/2mL Luer-Jet luer-lock pre-filled syringes (concentration 1mg/ml)
- Two mucosal atomization devices
- Product specific instructions
- Delaware Overdose Guidance document

Opioid Overdose Responders Action Steps:

- Recognize signs and symptoms of overdose
- Call for help – Dial 911
- IF NOT BREATHING: perform rescue breathing to provide oxygen
- Administer naloxone (see directions below)
- IF NO BREATHING OR SHALLOW BREATHING: continue rescue breathing
- If there is no change in 3-5 minutes, administer another dose (2nd box) of naloxone
- Stay with the person until help (medical professional) arrives

Administration of nasal naloxone:

Administer nasal naloxone to a person suspected of an opioid overdose with respiratory depression or unresponsiveness as follows:

1. Pop off the two caps from the delivery syringe and one cap from the naloxone vial.
2. Screw the naloxone vial gently into the delivery syringe.
3. Screw the mucosal atomizer device onto the top of the syringe.
4. Spray half (1ml) of the naloxone in one nostril and the other half (1ml) in the other nostril.
5. IF NO BREATHING OR SHALLOW BREATHING perform rescue breathing to provide oxygen
6. If there is no change in 3-5 minutes, administer another dose of naloxone (use another box)
7. Continue rescue breathing until person breathes for themselves or help arrives.
8. Remain with the person until he or she is under care of a medical professional, such as physician, nurse, or emergency medical technician.
9. Do not administer nasal naloxone to a person with known hypersensitivity to naloxone.

Refills: to be provided to Opioid Overdose Responders upon completion of a new Naloxone Acknowledgement Agreement form.

Tracking: Agencies providing training programs will maintain a registry of persons trained including, at minimum, the following information*:

- date trained, training site and trainer, number of persons trained
- naloxone preparation dispensed (intranasal or auto-injector device)
- type of dispensing done (first time issuance or replacement/refill)
- expiration date of dispensed preparation
- notification (by agency) of expiring preparation, re-training and refill opportunities
- naloxone use and outcome

Pharmacy will maintain records of training documentation with prescriptions filled under these standing orders.*

**This information will be made available to the CBNAP Program Coordinator from the CBNAP Program Liaisons as requested.*

Definitions

Community-Based Naloxone Access Program (CBNAP)

A program approved by Delaware Health and Social Services, Division of Public Health (DPH) to provide overdose response education and access to naloxone distribution services in accordance with these standing orders and program agreements.

Community-Based Naloxone Access Program Opioid Overdose Responder Training

An educational program which includes at a minimum: overdose prevention techniques, recognizing signs and symptom of overdose; calling 911, airway and breathing assessment; rescue breathing, naloxone storage, carrying and administration, post-overdose follow-up and care. This training may be provided by community-based classes, online videos, or by direct instruction from a pharmacist or other healthcare provider.

Program Medical Director:

The Director of the Division of Public Health, or their designee, as a physician licensed by the State of Delaware, with responsibility to provide medical oversight of the public health program in general, including clinical oversight of the Community-Based Naloxone Access Program (CBNAP), review and approval of the training program curriculum, and the appointment of the CBNAP Program Coordinator.

CBNAP Program Coordinator:

An employee of the state, appointed by the Director of the Division of Public Health to oversee and coordinate the implementation and monitoring of the CBNAP program and program agreements.

CBNAP Program Liaison:

An employee of the participating agency or pharmacy designated to serve as a single point of contact for coordination and communication with the CBNAP Program Coordinator.

Medication and Administration Device**Nasal Naloxone**

Pharmacology: Naloxone is a competitive narcotic antagonist, which reverses all effects of opioids (i.e. morphine and heroin), such as respiratory depression and central and peripheral nervous system effects.

Indications: Naloxone is indicated to reverse respiratory and central nervous system depression induced by opioids.

Onset/Duration: Following intranasal administration the onset of naloxone action is 3-5 minutes (but can take up to 8 minutes) with a peak in 12-20 minutes and duration of approximately 30-60 minutes.

Contraindications: Naloxone is contraindicated in patients known to be hypersensitive or to naloxone hydrochloride or to any of the other ingredients in Naloxone.

Warnings: Naloxone may induce opiate withdrawal in patients who are physically dependent. The severity and duration of the withdrawal syndrome are related to the dose of Naloxone and to the degree and type of opioid dependence.

Certain drugs such as propoxyphene (Darvon) may require much higher doses of naloxone for reversal than dispensed.

Adverse Reactions: Adverse reactions may include tachycardia, hypertension, dysrhythmias, nausea, vomiting, and diaphoresis.

Dosage / Intranasal Route: Administer (spray) half (1 ml, 1mg/1 ml) in one nostril and the other half (1 ml) in the other nostril.

Storage: Store at 20-25°C (68-77°F). Protect from light.

References

Massachusetts Department of Public Health. *Opioid Overdose Education and Naloxone Distribution. MDPH Naloxone Pilot Project Core Competencies.* 9/24/14

<http://www.mass.gov/eohhs/docs/dph/substance-abuse/core-competencies-for-naloxone-pilot-participants.pdf>

San Francisco Department of Public Health, Housing and Urban Health, *Drug Overdose and Prevention and Education Project. Standing Orders, 2009.* Harm Reduction Coalition, 9/24/14.

<http://harmreduction.org/wp-content/uploads/2012/02/Standing-Order-IN.pdf>

Community-Based Naloxone Access Program

Injectable IM (Intramuscular) Naloxone Distribution and Administration

Community Responder Naloxone (Narcan®) STANDING ORDERS (Single-Use Pre-filled Auto-Injector Device Alternative)

Approved for use by the Community-Based Naloxone Access Program's participating agencies, participating pharmacies, and trained responders

INDICATIONS: Respiratory distress as evidenced by slow respirations or no breathing (apnea), or unresponsiveness to stimuli (such as shaking, yelling or sternal rub.) This protocol will allow trained Opioid Overdose Responders to treat persons with a history based on bystanders, or Responder's prior knowledge of the person, or suspicion of potential opioid overdose as evidenced by nearby medications or drug paraphernalia.

Naloxone (naloxone hydrochloride) is indicated for reversal of opioid overdose in the setting of respiratory depression or no breathing (apnea) or unresponsiveness. It may be administered intramuscularly (IM) with the use of the single-use auto-injector device.

Order to dispense:

- This standing order authorizes approved Community-Based training programs and participating pharmacies to distribute IM naloxone kits to persons who have completed CBNAP Opioid Overdose Responder Training.
- This standing order authorizes approved Community-Based training programs to maintain supplies of IM naloxone kits for the purposes of distributing them as part of the Community-Based Naloxone Access Program.
- Pharmacists should consider offering training and IM naloxone kits to patients who have been prescribed 50 or more morphine milligram equivalents (MME) per day.
- Upon completion of CBNAP Training and documentation, dispense for use by an Opioid Overdose Responder an IM naloxone kit.

IM naloxone auto-injector kits contain the following, at a minimum:

- Two labeled (*to meet Board of Pharmacy standards*) naloxone hydrochloride pre-filled naloxone (0.4 mg/0.4 mL OR 2mg/0.4mL) single-use auto-injector devices
- One Auto-injector trainer (no needle, no medication, reusable)
- Product specific instructions
- Delaware Overdose Guidance document

Opioid Overdose Responders Action Steps:

- Recognize signs and symptoms of overdose
- Call for help – Dial 911
- IF NOT BREATHING: perform rescue breathing to provide oxygen
- Administer naloxone (see directions below)
- IF NO BREATHING OR SHALLOW BREATHING: continue rescue breathing

- If there is no change in 3-5 minutes, administer another dose (2nd auto-injector) of naloxone
- Stay with the person until help (medical professional) arrives

Administration of injectable IM naloxone:

Administer injectable naloxone to a person suspected of an opioid overdose with respiratory depression or unresponsiveness as follows:

1. Remove outer case from pre-filled single-use naloxone auto-injector device.
2. Follow printed instructions on device label or the electronic voice instructions.
3. Once (and only when) ready to use, remove red safety guard.
4. Place the black end of the auto-injector against the outer thigh (through clothing if necessary). Press firmly for 5 seconds while the naloxone is administered via auto-injection. *Injection will be intramuscular or subcutaneous depending on the patient's characteristics such as body fat percentage.*
5. IF NO BREATHING OR SHALLOW BREATHING, perform rescue breathing to provide oxygen.
6. If there is no change in 3-5 minutes, administer another dose of naloxone (use another single-use pre-filled naloxone auto-injector).
7. Continue rescue breathing until person breathes on own or help arrives.
8. Remain with the person until he or she is under care of a medical professional, such as physician, nurse or emergency medical technician.
9. Do not administer injectable naloxone to a person with known hypersensitivity to naloxone.
10. Dispose of the used auto-injector in a sharps container.

Refills: to be provided to Opioid Overdose Responders upon completion of a new Naloxone Acknowledgement Agreement form.

Tracking: Agencies providing training programs will maintain a registry of persons trained including, at minimum, the following information*:

- date trained, training site and trainer, number of persons trained
- naloxone preparation dispensed (intranasal or auto-injector device)
- type of dispensing done (first time issuance or replacement/refill)
- expiration date of dispensed preparation
- notification (by agency) of expiring preparation, re-training and refill opportunities
- naloxone use and outcome

Pharmacy will maintain records of training documentation with prescriptions filled under these standing orders.*

**This information will be made available to the CBNAP Program Coordinator from the CBNAP Program Liaisons as requested.*

Definitions

Community-Based Naloxone Access Program (CBNAP)

A program approved by Delaware Health and Social Services, Division of Public Health (DPH) to provide overdose response education and access to naloxone distribution services in accordance with these standing orders and program agreements.

Community-Based Naloxone Access Program Opioid Overdose Responder Training

An educational program which includes at a minimum: overdose prevention techniques, recognizing signs and symptom of overdose; calling 911, airway and breathing assessment; rescue breathing, naloxone storage, carrying and administration, post-overdose follow-up and care. This training may be provided by community-based classes, online videos, or by direct instruction from a pharmacist or other healthcare provider.

Program Medical Director:

The Director of the Division of Public Health, or their designee, as a physician licensed by the State of Delaware, with responsibility to provide medical oversight of the public health program in general, including clinical oversight of the Community-Based Naloxone Access Program (CBNAP), review and approval of the training program curriculum, and the appointment of the CBNAP Program Coordinator.

CBNAP Program Coordinator:

An employee of the state, appointed by the Director of the Division of Public Health to oversee and coordinate the implementation and monitoring of the CBNAP program and program agreements.

CBNAP Program Liaison:

An employee of the participating agency or pharmacy designated to serve as a single point of contact for coordination and communication with the CBNAP Program Coordinator.

Medication and Administration Device

Naloxone (EVZIO) Single-Use Pre-filled Device for Intramuscular Use

Pharmacology: Naloxone is a competitive narcotic antagonist, which reverses all effects of opioids (i.e. morphine and heroin), such as respiratory depression and central and peripheral nervous system effects.

Indications: Naloxone is indicated to reverse respiratory and central nervous system depression induced by opioids.

Onset/Duration: Following single EVZIO administration the maximum serum concentration is reached at 15 minutes (range 5 minutes to 1.2 hours). The mean plasma half-life in healthy adults was 1 ¼ hours (+/- ½ hr.).

Contraindications: Naloxone is contraindicated in patients known to be hypersensitive or to naloxone hydrochloride or to any of the other ingredients in Naloxone.

Warnings: Naloxone may induce opiate withdrawal in patients who are physically dependent. The severity and duration of the withdrawal syndrome are related to the dose of Naloxone and to the degree and type of opioid dependence. Certain drugs such as propoxyphene (Darvon) may require much higher doses of naloxone for reversal than dispensed.

Adverse Reactions: Adverse reactions may include tachycardia, hypertension, dysrhythmias, nausea, vomiting, and diaphoresis.

Dosage / Intramuscular or Subcutaneous Injection Route: 0.4 mg/0.4mL OR 2mg/0.4mL naloxone hydrochloride solution in a pre-filled single use auto-injector.

Storage: Store EVZIO in the outer case provided. Store at controlled room temperature at - 15°C to 25°C (59-77°F). Excursions permitted between 4°-40°C (between 39°-77°F).

References

EVZIO (naloxone hydrochloride injection) Auto-Injector for intramuscular or subcutaneous use. *Highlights of Prescribing Information*. Reference ID: 3482803. kaleo, Inc. Richmond, VA. 4/2014.

EVZIO (naloxone hydrochloride injection) 0.4 mg auto injector. <http://evzio.com/hcp/index.php>
Product website accessed 2/21/15.

Community-Based Naloxone Access Program

Naloxone Nasal Spray Distribution and Administration

Community Responder Naloxone STANDING ORDERS (Nasal Spray Alternative)

Approved for use by the Community-Based Naloxone Access Program's participating agencies, participating pharmacies, and trained responders

INDICATIONS: Respiratory distress as evidenced by slow respirations or no breathing (apnea), or unresponsiveness to stimuli (such as shaking, yelling or sternal rub.) This protocol will allow trained Opioid Overdose Responders to treat persons with a history based on bystanders, or Responder's prior knowledge of the person, or suspicion of potential opioid overdose as evidenced by nearby medications or drug paraphernalia.

Naloxone (naloxone hydrochloride) is indicated for reversal of opioid overdose in the setting of respiratory depression or no breathing (apnea) or unresponsiveness. It may be administered intranasally with the use of a single-use nasal spray device.

Order to dispense:

- This standing order authorizes approved Community-Based training programs and participating pharmacies to distribute naloxone nasal spray kits to persons who have completed CBNAP Opioid Overdose Responder Training.
- This standing order authorizes approved Community-Based training programs to maintain supplies of naloxone nasal spray kits for the purposes of distributing them as part of the Community-Based Naloxone Access Program.
- Pharmacists should consider offering training and naloxone nasal spray kits to patients who have been prescribed 50 or more morphine milligram equivalents (MME) per day.
- Upon completion of CBNAP Training and documentation, dispense for use by an Opioid Overdose Responder a naloxone nasal spray kit.

Naloxone nasal spray kits contain the following at a minimum:

- Two labeled (*to meet Board of Pharmacy standards*) naloxone hydrochloride (4 mg/0.1 mL) pre-filled nasal spray applicators
- Product specific instructions
- Delaware Overdose Guidance document

Opioid Overdose Responders Action Steps:

- Recognize signs and symptoms of overdose
- Call for help – Dial 911
- IF NOT BREATHING: perform rescue breathing to provide oxygen
- Administer naloxone (see directions below)
- IF NO BREATHING OR SHALLOW BREATHING: continue rescue breathing
- If there is no change in 3-5 minutes, administer another dose (2nd applicator) of naloxone
- Stay with the person until help (medical professional) arrives

Administration of naloxone nasal spray:

Administer naloxone nasal spray to a person suspected of an opioid overdose with respiratory depression or unresponsiveness as follows:

1. Peel back the package to remove the device. Hold the device with your thumb on the bottom of the plunger and 2 fingers on the nozzle.
2. Place and hold the tip of the nozzle in either nostril until your fingers touch the bottom of the patient's nose.
3. Press the plunger firmly to release the dose into the patient's nose.
4. IF NO BREATHING OR SHALLOW BREATHING, perform rescue breathing to provide oxygen.
5. If there is no change in 3-5 minutes, administer another dose of naloxone (use another single-use pre-filled applicator).
6. Continue rescue breathing until person breathes on own or help arrives.
7. Remain with the person until he or she is under care of a medical professional, such as physician, nurse or emergency medical technician.
8. Do not administer injectable naloxone to a person with known hypersensitivity to naloxone.

Refills: to be provided to Opioid Overdose Responders upon completion of a new Naloxone Acknowledgement Agreement form.

Tracking: Agencies providing training programs will maintain a registry of persons trained including, at minimum, the following information*:

- date trained, training site and trainer, number of persons trained
- naloxone preparation dispensed (intranasal or auto-injector device)
- type of dispensing done (first time issuance or replacement/refill)
- expiration date of dispensed preparation
- notification (by agency) of expiring preparation, re-training and refill opportunities
- naloxone use and outcome

Pharmacy will maintain records of training documentation with prescriptions filled under these standing orders.*

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Community-Based Naloxone Access Program Opioid Overdose Responder Training

An educational program which includes at a minimum: overdose prevention techniques, recognizing signs and symptom of overdose; calling 911, airway and breathing assessment; rescue breathing, naloxone storage, carrying and administration, post-overdose follow-up and care. This training may be provided by community-based classes, online videos, or by direct instruction from a pharmacist or other healthcare provider.

Program Medical Director:

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CBNAP Program Coordinator:

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CBNAP Program Liaison:

An employee of the participating agency or pharmacy designated to serve as a single point of contact for coordination and communication with the CBNAP Program Coordinator.

Medication and Administration Device**Naloxone (Narcan®) Nasal Spray for intranasal Use Only**

Pharmacology: Naloxone is a competitive narcotic antagonist, which reverses all effects of opioids (i.e. morphine and heroin), such as respiratory depression and central and peripheral nervous system effects.

Indications: Naloxone is indicated to reverse respiratory and central nervous system depression induced by opioids.

Contraindications: Naloxone is contraindicated in patients known to be hypersensitive or to naloxone hydrochloride or to any of the other ingredients in Naloxone.

Warnings: Naloxone may induce opiate withdrawal in patients who are physically dependent. The severity and duration of the withdrawal syndrome are related to the dose of Naloxone and to the degree and type of opioid dependence.

Certain drugs such as propoxyphene (Darvon) may require much higher doses of naloxone for reversal than dispensed.

Adverse Reactions: Adverse reactions may include tachycardia, hypertension, dysrhythmias, nausea, vomiting, and diaphoresis.

Dosage / Intramuscular or Subcutaneous Injection Route: 4 mg/0.1mL naloxone hydrochloride solution in a pre-filled single use nasal spray.

Storage: Store in the blister and cartons provided. Store at controlled room temperature at - 15°C to 25°C (59-77°F). Excursions permitted up to 40°C (104°F). Do not freeze. Protect from light.

References

Narcan Nasal Spray (naloxone hydrochloride nasal spray) 4.0 mg nasal spray. <https://www.narcan.com/>
Product website accessed 09/25/17.